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APPLICATION NUMBER 101 FILING DATE 01/17/97 FIRST NAMED APPLICANT

08/785,532 01/17/97 GRAY

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EXAMINER

HM21/0527

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LINEAR 3 ART UNIT PAPER NUMBER

1642 11  
1642

DATE MAILED: 05/27/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 3-13-98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

Claim(s) 26-41, 45-63 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) 26-41, 45-63 are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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1. The Amendment filed March 13, 1998 (Paper No. 10) response to the Office Action of September 9, 1997 (Paper No. 7) is acknowledged and has been entered. Previously pending claim 26 has been amended and new claims 48-63 have been added. Claims 26-41 and 45-63 are currently being examined.

2. It is noted that Applicant's telephone election of Group II, claims 26-41 and 45-47 was made with traverse. Applicant's election with traverse of Group II, claims 26-41 and 45-47 in Paper No 10 is acknowledged. The traversal is on the ground(s) that the search of all the groups would not impose a serious burden on the examiner. This is not found persuasive because the inventions are classified differently, necessitating different searches in the US Patent Office. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search because different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

3. Upon review and reconsideration and in view of the newly added claims, restriction to one of the following inventions is required under 35 U.S.C. § 121:

**Group I.** Claims 26-40 and 48-63 are drawn to a method of screening for neoplastic cells comprising contacting a nucleic acid with a polynucleotide probe, classified in Class 435, subclass 6.

**Group II.** Claims 26 and 41 are drawn to a method of screening for neoplastic cells and for identifying mutations comprising contacting a nucleic acid with a polynucleotide probe, classified in Class 435, subclass 6.

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**Group I.** Claims 45-47 are drawn to a method of detecting cancer by detecting the over expression of a protein, classified in Class 435, subclasses 4 and 7.1.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Group I is further subject to election of a single disclosed species.

Claims 26 and 48-60 are generic to a plurality of disclosed patentably distinct species comprising polynucleotide probes with different sequences, structures and functions that hybridize to different nucleic acid sequences wherein the probe sequences are selected from the group consisting of (A) SEQ ID Nos. 1-12 and 45 (claims 26 and 29-40) and (B) polynucleotide sequences that hybridize to SEQ ID Nos. 1-12 and 45 (claims 26 and 48-60).

(A) If species (A) is elected then claim 26 is subject to election of a single disclosed species.

Claim 26 is generic to a plurality of disclosed patentably distinct species comprising polynucleotide probes with different sequences, structures and functions that hybridize to different nucleic acid sequences wherein the probe sequences are

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selected from the group consisting of (a) SEQ ID NO: 1, (b) SEQ ID NO: 2, © SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ ID NO: 9, (j) SEQ ID NO: 10, (k) SEQ ID NO: 11, (l) SEQ ID NO: 12, (m) SEQ ID NO: 45. Claims 29-40 will be examined as they are drawn to the elected species.

(B) If species (B) is elected, then the species is subject to election of a single disclosed species.

Claim 26 is generic to a plurality of disclosed patentably distinct species comprising polynucleotide probes with different sequences, structures and functions that hybridize to different nucleic acid sequences wherein the probe sequences are selected from the group consisting of (a) SEQ ID NO: 1, (b) SEQ ID NO: 2, © SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ ID NO: 9, (j) SEQ ID NO: 10, (k) SEQ ID NO: 11, (l) SEQ ID NO: 12, (m) SEQ ID NO: 45. Claims 48-60 will be examined as they are drawn to the elected species.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of

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at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 USC 132 or which otherwise require a signature may be used by the applicant and should be addressed to [lila.feisee@uspto.gov](mailto:lila.feisee@uspto.gov).

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All internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of USC 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

May 19, 1998

  
LILA FEISEE  
SUPERVISORY PATENT EXAMINER